REMARKS

Claims 1-6 and 10-12 are pending in the application. Claims 1, 9, 10, and 12 are in independent form.

Claims 1-6 stands rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which, was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Office Action states that the specification fails to support the administration of an agent orally or by inhalation, since the mode of administration is agent dependent and thus, the agent is unknown. With regard to this assertion, in In Re Alton, 76 F.3d 1168, the Court states that, "if a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if [not] every nuance of the claims are explicitly described in the specification, then the adequate written description requirement is met." This is further upheld in Fujikawa v. Wattanasin, 93 F.3d 1559, wherein the Court states that, "[I]*psis verbis* disclosure is not necessary to satisfy the written description requirement of §112. Instead, the disclosure need only reasonably convey to persons skilled in the art that the inventor had possession of the subject matter in question." Additionally, in Hyatt v. Boone, 146 F.3d 1348, the Court states that, "thus, the written description must include all of the limitations of the interference, or the Applicant must show that in the absent text is necessarily comprehended in the description provided and would have been so understood at the time the patent application was filed."

It is therefore, respectfully requested that the present rejection be reconsidered because the application as filed, does contain sufficient support for the claims as currently pending. Specifically, the application as filed, at page 6, lines 5-15, discloses methods of administrating an agent for treating RSV infection. Preferably, the agent will be administered to the epithelial cells either intranasally or orally. Further, the application at page 7, lines 21-23 discloses that the gene therapy of the present invention is administered to the airways,

e.g. nose, sinus, throat, and lung, for example, as nose drops, by nebulization, vaporization, or other methods known in the art. Finally, the application as filed, discloses at page 13, lines 14-18, that the composition of the present invention can be administered orally to the patient using conventional methods and known techniques for delivering the compound orally while retaining biological activity. Examples of such dosages are disclosed throughout the application. The application as filed, thus met the written description requirement.

Further, the application as filed enables the claims as pending. The enablement requirement as stated by the courts, especially the court in Fiers v. Revel, 984 F.2d 1164, is that "an application meets the enablement requirement when it sets forth the detailed teaching of a method and there is no evidence impeaching the truth of the statements in the application." The court in George v. Bernier, 768 F.2d 1318, states that, "a patent must contain a description that enables one skilled in the art to make and use the invention. . . an inventor need not come out, however, explain every detail since he is speaking to those skilled in the art." Additionally, Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 211 U.S.P.Q. 81 (Fed. Cir. 1986), states that enablement, "is not precluded, even if some experimentation is necessary, although the amount of experimentation needed, must not be unduly extensive." The experimentation required the present invention is limited at most. This is because methods of oral and nasal administration are well known to those of skill in the art. In light of the above, reconsideration of the rejection is respectfully requested.

Claims 1, 2, 3, and 10-12 are rejected under §102(b) as being anticipated by the Patel, et al. patent. Reconsideration of the rejection under 35 U.S.C. §102(b), as anticipated by the Patel, et al. patent, as applied to the claims is respectfully requested. Anticipation has always been held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference.

The Office Action states that the Patel, et al. reference teaches that respiratory epithelial cells are the primary target cells for RSV infection. The respiratory epithelial cells produce pro-inflammatory and immunoregulatory cytokines and express adhesion molecules, suggesting that the respiratory

epithelial cell may be the most important cell to regulate the initial stages of inflammation and host immune responses in the microenvironment of the respiratory mucosa. Further, the Patel, et al. reference teaches that simultaneous incubation of infectious purified RSV with sIL-1r resulted in a significant reduction in enhancement of ICAM-1 expression. This therefore suggests that sIL-1r blocks ICAM-1 expression.

In other words, the Patel et al reference concerns the role of IL-1α in RSV-induced ICAM-1 expression. The experiments of Patel et al suggest that ICAM-1 expression is decreased by blocking sIL-1R with inactivated RSV or, live RSV and neutralizing antibodies to IL-1α, IL-1β or TNF-α. One skilled in the art would anticipate that decreasing sIL-1 expression would reduce expression of ICAM-1. From these results alone one of skill in the art would NOT anticipate or predict that blocking ICAM-1 expression can reduce the severity of RSV disease.

In contradistinction, the presently pending independent claims claim a method for treating respiratory infection by administering a blocker that down-regulates ICAM-1 expression and decreases replication of RSV and thus decreases respiratory viral infection. The presently pending independent claims also claim a method for treating respiratory infection by administering a blocker that down-regulates ICAM-1 expression and respiratory viral infection.

More specifically, the present invention, as claimed in the presently pending independent claims, claims that by blocking ICAM-1, the viral replication and spread in the epithelial cells of the lungs is limited. The antiviral mechanism of the ICAM-1 antibody or soluble ICAM-1 has not been previously demonstrated. The significant reduction in the number of infected cells or in viral titers of infected cultures leads to the reduction of ICAM-1 and other pro-inflammatory cytokines such as IL-1β. This finding enables the use of blockers of ICAM-1 for the purpose of limiting viral titers, similar to that of a vaccine. That the blockers function in a manner similar to that of a vaccine was neither shown nor suggested by the Patel, et al. reference. Therefore, the Patel, et al. reference does not establish a method for attenuating RSV infection by blocking ICAM-1 and it does not lend itself to be anticipatory that

blocking ICAM-1 can decrease viral titers. Thus, the presently pending independent claims are patentable over the Patel, et al. reference. Reconsideration of the rejection is respectfully requested.

Claims 1 and 2 are rejected under §102(b) as being anticipated by the Kumasaka, et al. patent. Reconsideration of the rejection under 35 U.S.C. §102(b), as anticipated by the Kumasaka, et al. patent, as applied to the claims is respectfully requested. Anticipation has always been held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference.

The Office Action states that the Kumasaka, et al. reference teaches that antisense oligonucleotides inhibited upregulation of ICAM-1 expression induced by intratracheal instillation of endotoxin into the distal airway, subsequently preventing the acute inflammatory response. It is undisputed that the Kumasaka, et al. reference teaches that antisense oligonucleotides inhibited upregulation of ICAM-1 expression by instillation of endotoxin. The effect of endotoxin is not equivalent to the effect of RSV. Endotoxins are typically produced by gram negative bacteria and RSV does not produce endotoxins. The Kumasaka, et al. reference does not pertain to RSV infection, nor does it pertain to a viral respiratory infection and methods of preventing and treating such an infection. In contradistinction, the presently pending independent claims claim a method for treating respiratory infection by administering a blocker that down-regulates ICAM-1 expression and respiratory viral infection. This is neither taught nor disclosed by the Kumasaka, et al. reference. Therefore, the presently pending claims are patentable over the Kumasaka, et al. reference and reconsideration of the rejection is respectfully requested.

The remaining dependent claims not specifically discussed herein are ultimately dependent upon the independent claims. References as applied against these dependent claims do not make up for the deficiencies of those references as discussed above. The prior art references do not disclose the characterizing features of the independent claims discussed above. Hence, it is respectfully submitted that all of the pending claims are patentable over the prior art.

It is respectfully requested that the present amendment be entered in order to place the application in condition for allowance or at least in better condition for appeal. The application is placed in condition for allowance as it addresses and resolves each and every issue that remains pending. Claims have also been amended to clearly distinguish over the prior art. The application is made at least in better condition for appeal as the amendment removes many issues thereby simplifying the issues on appeal. Further, the claims have been amended to more specifically define the invention while raising no new issues that would require any further searching. Rather, the amendments have been made in view of comments made in the Office Action that clearly distinguish the presently pending claims over the cited prior art. Hence, it is respectfully requested that the amendment be entered.

This amendment could not have been made earlier as the amendment further defines the claims over the prior art in accordance with the suggestion made in the Office Action, the suggestion first being made in the outstanding Office Action. Hence, since there remain no further issues to be resolved, it is respectfully requested that the present amendment be entered.

In conclusion, it is respectfully requested that the present amendment be entered in order to place the application in condition for allowance, which allowance is respectfully requested.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

KOHN & ASSOCIATES, PLLC

Amy E. Rinaldo
Registration No. 45,791
30500 Northwestern Hwy
Suite 410
Farmington Hills, MI 48334
(248) 539-5050

Dated: January 21, 2003

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231 on January 21, 2003.

Connie Herty

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

1. (Amended) A method of [preventing] attenuating a viral respiratory infection by administering an effective amount of a[n] blocker agent for blocking and down-regulating ICAM-1 expression and viral respiratory infection in a pharmaceutically acceptable carrier, thereby preventing viral respiratory infection.

9. (Amended) A method of preventing RSV infection by administering an effective amount of a[n agent] blocker that [interferes with] blocks the binding of RSV to ICAM-1, thereby preventing RSV infection.

10. (Amended) A method of [preventing] attenuating RSV infection by administering an effective amount of a[n agent] blocker that down regulates and blocks the expression of ICAM-1, thereby decreasing RSV binding to ICAM-1 and preventing RSV infection.